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providing a medical device, said medical device comprising (a) a reservoir comprising a polymer matrix portion and an antimicrobial agent disposed within said polymer matrix portion and (b) a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said device; and
implanting said medical device within the body of a patient for a period of at least three months.

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21. (Amended) A method of constructing a medical device comprising:

forming a reservoir comprising (a) a polymer matrix portion and (b) an antimicrobial agent disposed within said polymer matrix portion; and

providing a surfactant region comprising a surfactant over said reservoir at an outer surface of said device,

wherein said medical device is adapted for long-term implantation within the body of a patient.

Please add new claims 30 and 31 as follows:

a6
30. (Newly added) The medical device of claim 1, wherein said medical device is a urine contacting medical device.

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31. (Newly added) The medical device of claim 1, wherein said medical device is a blood contacting medical device.

REMARKS

Claim Amendments

Claims 1-31 are presently pending.

By the above amendment, claims 1, 6, 8, 12-15 and 21 are amended, and claims 30 and 31 have been added. Support for new claims 30 and 31 can be found in paragraph [0025] of the present specification.

A separate sheet entitled "Version with Markings to Show Changes Made" is provided to illustrate the amendment of claims 1, 6, 8, 12-15 and 21, and the addition of

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claims 30 and 31. Unamended claims 2-5, 7, 9-11, 16-20 and 22-29 are also included for the Examiner's convenience.

Response to Office Action

1. Rejection of Claims under 35 U.S.C. 112, second paragraph

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as indefinite due to the recitation of the phrase "said antiseptic agent", which is objected to as lacking antecedent basis.

Claim 12 has been amended to change the dependency of claim 12 from "claim 1" to --claim 11--. As a result, it is respectfully submitted that proper antecedent basis is presently provided by claim 12.

Accordingly, reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. 112, second paragraph are requested.

2. Rejection of Claims under 35 U.S.C. 102(b)

Claims 1-4, 7, 10-11, 21-22, 25-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanes et al. (U.S. Patent No. 5,855,913). This rejection is respectfully traversed for the reasons to follow.

Hanes et al. discloses *particles* incorporating surfactants for pulmonary drug delivery (e.g., by *inhalation*). See the Title, Abstract and col. 3, lines 33-55 of Hanes et al..

In contrast, as amended, independent claims 1 and 21 presently require via non-preamble claim limitations, *medical devices* that are adapted for long-term *implantation* within the body of a patient. As noted at paragraph [0024] of the present specification, "long-term" implantation refers to implantation for a period greater than three months.

It is respectfully submitted that independent claims 1 and 21, which are directed to (a) medical devices for (b) long term implantation, are neither anticipated by nor obvious in view of Hanes et al., which is directed to (a') particles for (b') inhalation.

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Claims 2-4, 7, 10-11, 22, 25, 26 and 28 depend, either directly or indirectly, from claim 1 or claim 21 and are therefore patentable over Hanes et al. for at least the reasons set forth above in connection with claims 1 and 21.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-4, 7, 10-11, 21-22, 25-26 and 28 as being anticipated by Hanes et al. are respectfully requested.

3. Rejections under 35 U.S.C. 103(a)

Claims 9, 12, 23, 24, and 29

Claims 9, 12, 23, 24, and 29 are rejected under 35 U.S.C. 103(a) as being obvious in view of Hanes et al. These rejections are respectfully traversed for the reasons to follow.

As noted above claims 1 and 21 are neither anticipated by nor obvious in view of Hanes et al., because these claims presently require, via non-preamble claim limitations, *medical devices* that are adapted for long-term *implantation* within the body of a patient, while Hanes et al., on the other hand, is directed to *particles* incorporating surfactants for *inhalation* by a patent.

Claims 9, 12, 23, 24, and 29 depend from independent claim 1 or independent claim 21 and are therefore patentable over Hanes et al. for at least the same reasons.

Accordingly, reconsideration and withdrawal of the rejection of claims 9, 12, 23, 24, and 29 as being obvious in view of Hanes et al. are respectfully requested.

Claims 5, 6 and 27

Claims 5, 6 and 27 are rejected under 35 U.S.C. 103(a) as being obvious over Hanes et al. in view of Vacheethasanee et al.

It is respectfully submitted that Vacheethasanee et al., which is cited for its disclosure of surfactant polymers, does not make up for the above-noted deficiencies in Hanes et al. Accordingly, independent claims 1 and 21 are unobvious over Hanes et al. and Vacheethasanee et al. for the reasons set forth above.

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Claims 5, 6 and 27 depend from independent claim 1 or independent claim 21 and are therefore patentable over Hanes et al. and Vacheethasanee et al. for at least the same reasons.

Accordingly, reconsideration and withdrawal of the rejection of claims 5, 6 and 27 as being obvious over Hanes et al. in view of Vacheethasanee et al. are respectfully requested.

4. Claims 8, 13, 14 and 15-20

The applicants note with appreciation the indication of allowable subject matter in claims 15- 20.

The applicants have also amended claims 8 and 13-14 to include the limitations of the base claim as suggested in the Office Action. Accordingly, it is respectfully submitted that these claims are in a condition for allowance as well.

CONCLUSION

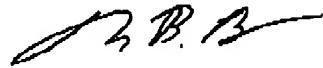
Applicants submit that claims 1-31 are presently in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

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FEES

The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

Respectfully submitted,



David B. Bonham
Registration No. 34,297

Attorney for Applicant
Mayer Fortkort & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

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David B. Bonham

(Printed Name of Person Mailing Correspondence)


(Signature)

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Version With Markings To Show Changes Made

IN THE CLAIMS:

1. (Amended) A medical device for long-term implantation comprising:
a reservoir comprising (a) a polymer matrix and (b) an antimicrobial agent disposed within said polymer matrix, said reservoir adapted for long-term release of said antimicrobial agent from said polymer matrix; and
a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said medical device,
wherein said medical device is adapted for long-term implantation within the body of a patient.
2. The medical device of claim 1, wherein said surfactant is a biosurfactant.
3. The medical device of claim 2, wherein said biosurfactant is selected from glycolipids, lipopeptides, depsipeptides, phospholipids, substituted fatty acids, and lipopolysaccharides.
4. The medical device of claim 2, wherein said biosurfactant is selected from surlactin, surfactin, visconsin and rhamnolipids.
5. The medical device of claim 1, wherein said surfactant is a surfactant polymer.
6. (Amended) The medical device of claim 5, wherein said surfactant polymer is a surfactant polymer having a poly(vinyl amine) backbone and having hydrophilic poly(ethylene oxide) and hydrophobic hexanal side chains.-

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7. The medical device of claim 1, wherein said surfactant is linked by one or more interactions selected from hydrophobic interactions, ionic interactions and covalent interactions.
8. (Amended) A medical device for long-term implantation comprising: (1) a reservoir comprising (a) a polymer matrix and (b) an antimicrobial agent disposed within said polymer matrix, said reservoir adapted for long-term release of said antimicrobial agent from said polymer matrix; and (2) a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said device.
The medical device of claim 1, wherein said medical device is selected from a ureteral stent and a urethral catheter.
9. The medical device of claim 1, wherein said antimicrobial agent is selected from triclosan, chlorhexidine, silver sulfadiazine, silver ions, benzalkonium chloride and zinc pyrithione.
10. The medical device of claim 1, wherein said antimicrobial agent is a broad-spectrum antibiotic.
11. The medical device of claim 1, wherein said antimicrobial agent is an antiseptic agent.
12. (Amended) The medical device of claim 1, wherein said antiseptic agent is iodine.
13. (Amended) A medical device for long-term implantation comprising: (1) a reservoir comprising (a) a polymer matrix and (b) an antimicrobial agent disposed within said polymer matrix, said reservoir adapted for long-term release of said antimicrobial agent from said polymer matrix; (2) a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said device; and

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~~The medical device of claim 1, further comprising (3) a barrier layer disposed between said polymer matrix and said surfactant region.~~

14. (Amended) A medical device for long-term implantation comprising: (1) a reservoir comprising (a) a polymer matrix ~~The medical device of claim 1, wherein said polymer matrix comprises~~ comprising a polymer selected from an ethylene-vinyl acetate copolymer and a polyurethane ~~and (b) an antimicrobial agent disposed within~~ said polymer matrix, said reservoir adapted for long-term release of said antimicrobial agent from said polymer matrix; and (2) a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said device.

15. (Amended) A method of treatment comprising:

providing a medical device, said medical device comprising (a) a reservoir comprising a polymer matrix portion and an antimicrobial agent disposed within said polymer matrix portion and (b) a surfactant region comprising a surfactant, said surfactant region disposed over said reservoir at an outer surface of said device; and implanting said medical device within the body of a patient for a period of at least three months.

16. The method of claim 15, wherein said surfactant is a biosurfactant.

17. The method of claim 15, wherein said surfactant is a surfactant polymer.

18. The method of claim 15, wherein said medical device is selected from a ureteral stent and a urethral catheter.

19. The method of claim 15, wherein said polymer matrix comprises a polymer selected from an ethylene-vinyl acetate copolymer and a polyurethane.

20. The method of claim 15, wherein said device is implanted in a urine-contacting area.

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21. (Amended) A method of constructing a medical device comprising:
 - forming a reservoir comprising (a) a polymer matrix portion and (b) an antimicrobial agent disposed within said polymer matrix portion; and
 - providing a surfactant region comprising a surfactant over said reservoir at an outer surface of said device,
wherein said medical device is adapted for long-term implantation within the body of a patient.
22. The method of claim 21, wherein said antimicrobial agent is disposed within said polymer matrix at the time of formation of said polymer matrix.
23. The method of claim 22, wherein said antimicrobial agent is co-cast with said polymer matrix.
24. The method of claim 22, wherein said antimicrobial agent is co-extruded with said polymer matrix.
25. The method of claim 21, wherein said antimicrobial agent is provided within said polymer matrix by imbibing said antimicrobial agent into said polymer matrix.
26. The method of claim 21, wherein said surfactant is a biosurfactant.
27. The method of claim 21, wherein said surfactant is a surfactant polymer.
28. The method of claim 21, wherein said surfactant is covalently linked at said outer surface of said device.
29. The method of claim 21, wherein said antimicrobial agent is selected from triclosan, chlorhexidine, silver sulfadiazine, silver ions, benzalkonium chloride and zinc pyrithione.

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30. (Newly added) The medical device of claim 1, wherein said medical device is a urine contacting medical device.

31. (Newly added) The medical device of claim 1, wherein said medical device is a blood contacting medical device.